

## REMARKS

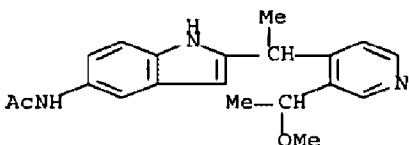
### Status of the Claims

No claims have been amended. Claims 25, 28 – 34, and 38 – 46 are presently pending.

### Rejections under 35 U.S.C. 102 (b)

#### (a) Claims 25, 42, and 43 over Sainsbury et al.

Claims 25, 42, and 43 currently stand rejected in light of the compound,



as disclosed in Sainsbury, et al. In the present action, the Office has alleged that the preceding compound reads on the present claims when L<sup>11</sup> is a bond; R<sup>11</sup> is H; R<sup>33</sup> is H; R<sup>44</sup> is an optionally substituted C<sub>1-6</sub> alkyl group; and **R<sup>22</sup> is a substituted ethyl group**. The Office claims that since there is “no definition in the specification of the term ‘C<sub>1-6</sub>alkyl’,” that the “broadest possible interpretation in light of the specification [is] substituted or unsubstituted C<sub>1-6</sub>alkyl.” Applicants respectfully traverse.

Applicants note that according to MPEP 2111.01 (II), (emphasis added)

“[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a **person of ordinary skill in the art in question at the time of the invention**, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, \*415 F.3d 1303, 1313<, 75 USPQ2d 1321>, 1326< (Fed. Cir. 2005) (*en banc*). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)

The ordinary and customary meaning of a term may be evidenced by a variety of sources, including “**the words of the claims themselves, the remainder of the specification**, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” <*Phillips v. AWH Corp.*, \*415 F.3d at 1314<, 75 USPQ2d \*\*>at 1327.<

In the present case, the specification states at paragraph [0068], emphasis added,

As employed herein, **when a moiety** (e.g., cycloalkyl, hydrocarbyl, aryl, heteroaryl, heterocyclic, urea, etc.) is described as “optionally substituted” it is meant that the group optionally has from one to four, preferably one to three, more preferably one to two, non-hydrogen substituents.

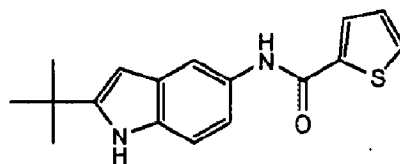
Applicants submit that the specification clearly states that the term “optionally substituted” only applies to a term, such as “alkyl,” **when the moiety is so named** (e.g., “optionally substituted C<sub>1-6</sub>alkyl”). Herein, the absence of the term “optionally substituted,” when interpreted in light of the specification, means that the C<sub>1-6</sub> alkyl group is not substituted.

Furthermore, the applicants use of the term "optionally substituted" in the definition of R<sup>44</sup>. To construe moieties such as “C<sub>1-6</sub> alkyl” to include "optionally substituted C<sub>1-6</sub> alkyl” would be to make the term "optionally substituted" meaningless.

Accordingly, the present rejection over Sainsbury, *et al.* is improper as the claims to not read on the allegedly anticipatory compound, that is, R<sup>22</sup> is not a “substituted C<sub>1-6</sub>alkyl”. Applicants respectfully request reconsideration and withdrawal of the rejection.

**(b) Claims 25, 28, 29, 42 – 46 over Peakdale catalog compound from IDS**

Claims 25, 28, 29, 42 – 46 currently stand rejected in light of the compound,



as disclosed in the Peaksdale catalog and as disclosed in the IDS filed on 9/20/2007. In the present action, the Office has alleged that the preceding compound reads on the present claims when L<sup>11</sup> is a bond; R<sup>11</sup> is H; R<sup>33</sup> is H; R<sup>44</sup> is an optionally substituted monocyclic heteroaryl; and R<sup>22</sup> is a t-butyl group. Furthermore, the Office has stated their rejection of claims directed to a composition comprising a compound, as defined herein, and a pharmaceutically acceptable carrier, excipient, or diluent, that, “[t]he Office **presumes** the compound is in solution as a composition. A pharmaceutical carrier **could be** water.” See, Office Action at page 5. Applicants respectfully traverse.

Applicants note that according to MPEP 2131, (emphasis added),

“A claim is anticipated **only if** each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Furthermore, according to MPEP 2112 (IV), (emphasis added),

The fact that a certain result or characteristic **may occur or be present** in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re*

*Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

(Emphasis added.)

In the instant case, the Office has not established that each and every element of the present claims is expressly described by the Peakdale catalog document. The Peakdale catalog does not provide any reference to a pharmaceutically acceptable carrier.

Furthermore, the Office has not provided scientifically based reasoning or extrinsic evidence establishing that the allegedly anticipatory composition of the disclosed compound in water is necessarily inherently present in a catalog listing of the compound.

Accordingly, Applicants submit that the present rejection is improper for failing to expressly or inherently disclose all the present claim limitations. Applicants respectfully request reconsideration and withdrawal of the rejection.

## **CONCLUSION**

Applicants respectfully submit that all requirements of patentability have been met. Allowance of the claims and passage of the case to issue are therefore respectfully solicited.

If the Examiner has any questions or comments regarding this Amendment, they are encouraged to contact the undersigned as indicated below.

Respectfully submitted,

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